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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/902,016	07/10/2001	David L. Thompson	P-9153.05	8319
27581	7590	11/18/2003	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604			JASMIN, LYNDIA C	
			ART UNIT	PAPER NUMBER
			3627	

DATE MAILED: 11/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/902,016

Applicant(s)

THOMPSON, DAVID L.

Examiner

Lynda Jasmin

Art Unit

3627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-26 and 30-32 is/are rejected.
- 7) ☐ Claim(s) 22 and 27-29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11/2,2. 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Drawings***

1. The informal drawings filed in this application are acceptable for examination purposes. When the application is allowed, applicant will be required to submit new formal drawings.

### ***Claim Objections***

2. Claim 2 is objected to because of the following informalities: at line 1, the term "an" should be --and--. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Regarding claims 4 and 5, the word "means" is preceded by the word(s) "to analyze" and "to select" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

***Double Patenting***

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 17-20, 25, 26, 30-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-9 of copending Application No. 09/775,281. Although the conflicting claims are not identical, they are not patentably distinct from each other because having an inventory and production control system synchronous with various phases of product manufacturing standard, customized and newly approved, modified/redesigned devices and utilizing an

inventory management system to select a user-specific configuration based on customized order achieved the same end result of utilizing an information network in data communication with manufacturing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1-3, 5-21, 23-26, 30-32 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7-9 of copending Application No. 09/775,262. Although the conflicting claims are not identical, they are not patentably distinct from each other because having a device manufacturing and supply information management for customized features with customized data set and utilizing an inventory management system to select a patient-specific configuration based on customized order achieved the same end result of utilizing an information network to received patient specific data for manufacturing.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Allowable Subject Matter***

9. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

10. Claims 22, 27-29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record fails to explicitly teach or fairly suggest a signal differentiation process including means for analyzing cardiac waveforms in combination with selecting configuration to test a manufacturing IMD.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dr. David M. Anderson, "Spontaneous Build-To-Order" Copyright 2001, <http://www.design4manufacturability.com> discloses the concept of quickly build standard customized products upon receipt of spontaneous orders without inventory or purchasing delays.

James Carbone, "Most OEMs Build-To-Order" April 1999, Purchasing Magazine Online discloses a build to order model system in electronic original equipment manufacturers.

Duffin et al. discloses a system and method for communication with a medical device implanted in an ambulatory patient and for locating the patient to monitor device function. The implanted device further includes a telemetry transceiver for communicating data between the device and an external patient communication control device.

Krichen et al. discloses a system and method for transferring information from an implantable device to a remote location. A programmer is electrically connected to the implantable medical device and is capable of temporarily saving selected information related the IMD and transferring the selected information to a remote location.

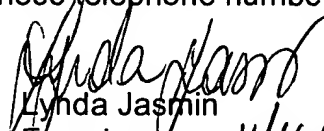
Linberg discloses a system and method for remote invoicing and inventory control of medical components of an IMD system upon implantation into a patient.

Vrhel et al. (6,543,047 B1) discloses a build-to-order manufacturing method for producing custom configured computer system.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lynda Jasmin whose telephone number is (703) 305-0465. The examiner can normally be reached on Monday- Friday (8:00-5:30) alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9326.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1113.

  
Lynda Jasmin  
Examiner  
Art Unit 3627  
11/16/03